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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/497,943	02/04/2000	Mark Aaron Behlke		8098
7590 11/26/2003			EXAMINER	
Robert M. Gould			SISSON, BRADLEY L	
VIce President Intellectual Property INTEGRATED DNA TECHNOLOGIES, INC			ART UNIT	PAPER NUMBER
8930 Gross Point Rd. Suite 700			1634	
Skokie, IL 60077			DATE MAILED: 11/26/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary						
		09/497,943	BEHLKE ET AL.			
		Examiner	Art Unit			
		Bradley L. Sisson	1634			
The MAILING DATE of this communication app ars on the cov r she t with the correspondence address Period for Reply						
THE - External after - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nations of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be within the statutory minimum of thirty (30) drill apply and will expire SIX (6) MONTHS frocause the application to become ABANDO	timely filed lays will be considered timely. om the mailing date of this communication. NED (35 U.S.C. § 133).			
1)⊠	Responsive to communication(s) filed on 28 Ag	<u>oril 2003</u> .				
2a)⊠	This action is FINAL . 2b) This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims					
 4) ☐ Claim(s) 29-41 and 43-57 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 29-41 and 43-57 is/are rejected. 7) ☐ Claim(s) 55-57 is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. 						
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9) ☐ The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
, _	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. §§ 119 and 120						
a)[* S 13)⊠ A si 3 3 a 14)	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau see the attached detailed Office action for a list ocknowledgment is made of a claim for domestic nice a specific reference was included in the first 7 CFR 1.78. 1 The translation of the foreign language processors are considered as included in the first sentence of the ference was included in the first sentence of the	s have been received. s have been received in Applicative documents have been received (PCT Rule 17.2(a)). of the certified copies not receive priority under 35 U.S.C. § 119 t sentence of the specification visional application has been receptority under 35 U.S.C. §§ 12	ved in this National Stage ved. (e) (to a provisional application) or in an Application Data Sheet. eceived.			
Attachment						
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)			

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DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Pages i and ii provide a table of contents where segments of the specification are identified via page numbers. Page numbers will not be retained in the issued patent, thereby rendering the table of contents confusing.

2. Appropriate correction is required.

Claim Objections

- 3. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.
- 4. A claim that depends from a dependent claim should not be separated by any claim that does not also depend from said dependent claim. In the present case, claims 55-57, which depend from claim 29, are separated from claim 29 by independent claims 49, 50, and 51. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 29-41, 43-48, and 50-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

For convenience, claim 29 is reproduced below.

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29. (Amended) A method of labeling a nucleic acid molecule, comprising the steps of:

- a. hybridizing a first nucleic acid to a second nucleic acid, wherein the
 first nucleic acid comprises, from 3' to 5': a Substrate Hybridization
 Domain and a Signal Template Domain, wherein:
 - the Substrate Hybridization Domain [comprises] consists of a sequence of [about 5 to about 20] less than 10 nucleotides; and

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ii. the Signal Template Domain comprises a sequence of about 5 to about 100 nucleotides;

and the second nucleic acid comprises from 3' to 5': a Template Hybridization Domain, and a Target Binding Domain, wherein:

- i. the Template I oxidization Domain [comprises] consists of a sequence of [out 5 to about 20] less than 10 nucleotides, is not detectably labeled, and shows complementarity toward and is hybridizable to the Substrate Hybridization Domain of the first nucleic acid;
- the Target Binding Domain is not detectably labeled and comprises a nucleotide sequence heterologous to that of the Template Hybridization Domain;

and:

- b. extending the second nucleic acid with a DNA polymerase in the presence of a labeled nucleotide to create an oligonucleotide having from 5' to 3' an unlabeled Target Binding Domain, a Template Hybridization Domain, and a labeled Signal Domain having a sequence which shows complementarity toward and is hybridizable to the Signal Template Domain. [, thereby labeling said second nucleic acid molecule.]
- 7. For purposes of examination, claim 29 has been interpreted as encompassing a "Substrate Hybridization Domain" and a "Template Hybridization Domain" which each consists of as few as 1 nucleotide. Support for this interpretation is based on the phase "less than 10 nucleotides," where a single nucleotide is the lower limit where each of the Domains would still exist.

Additionally, claim 29 has been interpreted as encompassing a "first nucleic acid" and a "second nucleic acid" that are each of virtually any length. Support for this interpretation is based on the use of the term "comprises." While claim 29 has been amended so to recite definite limits to the various domains, such language has not been interpreted as precluding the presence of any number of additional nucleotides that have similar or different properties, nor have said amendments been interpreted as placing any limits as to where said additional nucleotides occur in the first and second nucleic acids and their respective domains.

8. At page 4 of the response received 28 April 2003, applicant asserts in part:

Summary of the Amendments

Claim 29 has been amended to clarify that the Substrate and Template Hybridization Domains "consist of sequences of less than 10 nucleotides." Claim 34 has been amended to clarify that the Substrate Hybridization Domain also "consists of" sequences of "less than" 10 nucleotides. Support for these amendments can be found in the specification at page 19, line 6. Claim 29 has also been amended to clarify that the addition of labeled nucleotides by

A review of page 19, line 6, of the original disclosure finds the following:

A Substrate or Template Hybridization Domain of about 5 to about 20 bases in length is preferred, with a length of about 5 to about 10 bases in length being most preferred.

As noted above, the phrase "les than 10" has been interpreted as encompassing values of 1, if not zero. The range "about 5 to about 10 bases" is not considered to provide support for the lower limit of the range ascribed by the phrase "less than 10." Accordingly, the limitation is considered to constitute new matter. Claims 29-41, 43-48, and 55-57, which depend from claim 29, fail to overcome this issue and are similarly rejected.

9. Claim 51 was also amendment to recite the same phrase as that objected to in claim 29, supra. For the above reasons, and in the absence of convincing evidence to the contrary, claim

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51, and claims 52-54, which depend therefrom, are also rejected under 35 USC 112, first paragraph, as it relates to the introduction of new matter into the claims.

- 10. Claims 51-54 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- 11. For convenience, claim 51 has been reproduced below.

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51. (Amended) A kit for labeling a nucleic acid molecule, comprising a reaction mixture and a DNA polymerase, wherein the reaction mixture comprises:

- a. a first nucleic acid comprising, from 3' to 5': a Substrate Hybridization

 Domain and a Signal Template Domain, wherein:
 - the Substrate Hybridization Domain consists of a sequence of less than 10 nucleotides; and

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- ii. the Signal Template Domain comprises a sequence of about 5
 to about 100 nucleotides;
 and
- a second nucleic acid comprising, from 3* to 5*: a Template
 Hybridization Domain and a Target Binding Domain, wherein:
 - the Template Hybridization Domain consists of a sequence of less than 10 nucleotides, is not detectably labeled, and shows complementarity toward and is hybridizable to the Substrate Hybridization Domain of the first nucleic acid;
 - ii. the Target Binding Domain is not detectably labeled and comprises a nucleotide sequence heterologous to that of the Template Hybridization Domain;
- c. wherein the hybridization domains of the first and second nucleic acids hybridize to each other under conditions in which an enzyme can extend the second nucleic acid by adding a sequence complementary to the Signal Template Domain.

Claim 51, and claims 52-54 are all drawn to a kit that is comprised of a first and second nucleic acid. The claims have been interpreted as encompassing virtually a limitless number of such nucleic acids. Indeed, the claims fairly encompass oligonucleotides that fairly represent every segment of every chromosome of every life form that exists on or in the earth, as well as any other sequence or combination of sequences. A review of the disclosure fails to find an adequate written description of a representative number of embodiments so as to reasonably suggest that applicant, at the time of filing, was in possession of the full genus of nucleic acids now claimed.

In support of this position, attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

It would appear that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

12. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

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Response to arguments

13. At page 6 of the response of 28 April 2003, hereinafter the response, applicant asserts that the rejection should be withdrawn as the Federal Circuit has reversed its position as it relates to Enzo Biochem Inc. v. Gen-Probe Inc. (CAFC 01-1230, April 2002).

14. While agreement is reached in that the prior support based in *Enzo* is no longer available, the rejection is still being maintained as the disclosure does not reasonably suggest that applicant was in possession of the virtually limitless number of first and second nucleic acids that are encompassed by the claims.

Claim Rejections - 35 USC § 102

15. The rejection of claims 29, 30, 32, 33, 40, and 44 under 35 USC 102(e) as being anticipated by US Patent 5,882,856 (Shuber) is hereby withdrawn in view of the amendments to claim 29.

Claim Rejections - 35 USC § 103

- 16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 17. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 19. Claims 29, 30, 32-38, 40-46, 48-52, and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,882,856 (Shuber) in view of US Patent 5,710,028 (Eyal et al.).
- 20. For purposes of examination, claim 29 has been interpreted as encompassing a "Substrate Hybridization Domain" and a "Template Hybridization Domain" which each consists of as few as 1 nucleotide. Support for this interpretation is based on the phase "less than 10 nucleotides," where a single nucleotide is the lower limit where each of the Domains would still exist. Additionally, claim 29 has been interpreted as encompassing a "first nucleic acid" and a "second nucleic acid" that are each of virtually any length. Support for this interpretation is based on the use of the term "comprises." While claim 29 has been amended so to recite definite limits to the various domains, such language has not been interpreted as precluding the presence of any number of additional nucleotides that have similar or different properties, nor have said

amendments been interpreted as placing any limits as to where said additional nucleotides occur in the first and second nucleic acids and their respective domains.

- 21. In view of the foregoing interpretation of the various domains of the first and second nucleic acids, the "homopolymeric" limitation of claim 41 is considered to be met by the presence of but a single nucleotide.
- 22. Claim 54 has been interpreted for purposes of examination as encompassing a first nucleic acid that comprises the entire, as well as a fractional sequence of SEQ ID NO: 10. Said fractional sequence can be of virtually any segment of said SEQ ID NO: 10 and can also include any additional nucleotide sequence as is accorded by the use of "comprising."
- Shuber, column 2, third paragraph, and column 4, third paragraph, discloses the use of a chimeric primer that is described as being configured 5'-XY-3'. The "X" domain "comprises a sequence that does not hybridize to the target sequence." The "Y" domain "comprises a sequence contained within or flanking the target sequence or its complement." Accordingly, the "X" domain meets the limitations of applicants "Signal Template Domain" and the "Y" domain meets the limitations of the "Substrate hybridization Domain" of the "first sequence." The target sequence meets the limitations of applicant's second sequence.
- As seen at column 4, the respective domains may be comprised of nearly any nucleotide sequence and that it can range in length from 17 to 25 bases. As stated above, the first and second nucleic acids of he claimed method have been interpreted as encompassing any number of nucleotides, and that nucleotides beyond the limits recited for the various domains can be immediately adjacent to the nucleotides that make up said domains, and can have the same

property as those nucleotides that comprise said domains. Accordingly, the disclosure of first and second nucleic acids in the prior art that have an overall length greater than just the recited domains is still considered to meet the limitation of the first and second nuclei acids that are used in the claimed method and of which the kit is comprised.

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- 25. Shuber does not teach using RNA as a source material or the use of primers that comprise RNA. Additionally, Shuber et al., do not teach using labeled nucleotides and detecting their incorporation.
- 26. Eyal et al., column 3, teach explicitly of incorporating detectably-labeled nucleotides at the terminus of a primer so to label a nucleic acid molecule as well as to detect a target nucleic acid in a sample. As seen herein, the detectable label can be radioactive or fluorescent.
- 27. Eyal et al., column 4, teach that their method is "simple, rapid and highly accurate."
- 28. Eyal et al., column 4 and column 28 disclose providing kits. As seen in column 28, the kits can comprise any number of primers (applicant's first and second nucleic acids) as well as any and all other reagents.
- 29. Eyal et al., column 1, states that the starting material (at least one of applicant's "nucleic acids") is RNA. Column 9, first paragraph, teaches explicitly of the wide variety of detectably-labeled nucleotides that can be added to the terminus of a second nucleic acid. As seen therein, such nucleotides include ribonucleotides.

Neither Shuber nor Eyal et al., disclose the precise ratio or percentage of homopolymeric nucleotides present or the specific activity of the probes used, however, such limitations are considered to be the result of routine optimization and do not constitute a point of novelty.

Attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPO 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPO 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re-Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

30. In view of the explicit teachings of benefit (simple, rapid, highly accurate and widely applicable) as taught by Eyal et al., at column 4, one of ordinary skill in the art at the time the invention was made would have been motivated to have modified the method of Shuber such that the time consuming and laborious process of detecting primer extension products on a gel would be avoided by incorporating a detectable nucleotide at the terminus and then detect its incorporation and in so doing not only label a nucleic acid but to also detect a target nucleic acid of interest. It would have also been obvious to said ordinary artisan to have included said first and second nucleic acids in a kit for in addition to its being an obvious commercial expediency, such is also taught Eyal et al. Accordingly, and in the absence of convincing evidence to the contrary, claims 29, 30, 32-38, 40-46, 48-52, and 54-56 are rejected under 35 U.S.C. 103(a).

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31. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber and Eyal et al., as applied to claim29, 30, 32-38, 40-46, 48-52, and 54-56 above, and further in view of US Patent 5,599,708 (Mundy et al.) and US Patent 5,614,389 (Auerbach).

- 32. See above for the basis of the rejection as it relates to the disclosures of Shuber and Eyal et al.
- 33. Neither Shuber nor Eyal et al., disclose using a nucleic acid that comprises a hairpin loop.
- 34. Mundy et al., column 8, teaches performing multiple cycles of primer extension reactions, including reactions using mRNA templates that have a hairpin loop. As noted therein, the mRNA has a loop at its 3' terminus, yet the product of the primer extension reaction can be used in subsequent rounds of amplification. In such second rounds, the hairpin loop would occur at the 5' terminus (a limitation of claim 57).
- 35. Auerbach, Figure 3A, discloses applicant's first nucleic acid having a hairpin loop region that is 5' to the Signal Template Domain. It is noted that X and X' form the double stranded stem region when the nucleic acid exists in single-stranded form (see Figure 5).
- 36. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the first nucleic acid used in the primer extension reaction of Shuber with a nucleic acid that comprises are region known to contain a hairpin loop as Mundy et al., and Auerbach teaches explicitly of annealing a second nucleic acid to just such a first nucleic acid such that primer extension reaction can be conducted.

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37. In view of the detailed guidance, the broad applicability and motivation found in the art (Eyal et al.) the ordinary artisan would have been amply motivated to have labeled nucleic acids in such a manner and to have done so with a most reasonable expectation of success.

Conclusion

- Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 39. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
- 40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.
- 41. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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42. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bradley L. Sisson Primary Examiner Art Unit 1634

Q. L. Sinon

BLS

19 November 2003